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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,020	12/05/2001	Gary B. Gordon	10002431-4	5593

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AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P. O. Box 7599
Loveland, CO 80537-0599

EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,020	GORDON, GARY B.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-15 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>JULY'02</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: Figure 2 is not mentioned or described in the Specification. A proposed amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities:

a. The specification does not include a Brief Description of the Drawings as required under 37 C.F.R. 1.74.

b. The specification is further objected to because pages 6 through 11 are missing.

Applicant is reminded that amendments to the specification filed under 37 CFR 1.125(a) must only contain subject matter from the originally filed specification and any previously entered amendment under 37 CFR 1.121.

Appropriate correction is required.

Claim Objections

3. Claim 11 is objected to because the claim depends from itself. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 8-15 are indefinite in Claim 8 because the claim is drawn to a method of array hybridization but the claim does not recite hybridization method steps. As such, it is unclear whether the method accomplishes hybridization as claimed. It is suggested that Claim 8 be amended to clarify.

b. Claims 8-15 are indefinite in Claim 8 for the recitation "said reaction cell having a probe array" because the recitation lacks proper antecedent basis in the reaction cell of the preceding method step which is not limited to having a probe array. Therefore, it is unclear whether the reaction cell of the centrifugation step is referring to the previous reaction cell. It is suggested that Claim 8 be amended to clarify e.g. in line 2, after "reaction cell" insert, "having a probe array".

c. Claims 9 and 12 are each indefinite for the recitation "said sample cell" because the recitation lacks proper antecedent basis in the reaction cell of Claim 8. It is suggested that Claim 9 and 12 be amended to provide proper antecedent basis.

Art Unit: 1634

d. Claim 12 is indefinite for the recitation "about an agitation axis that extends more parallel to said centrifuge axis" because "more" is a comparative term but it is unclear to what the axis is being compared. It is suggested that claim 12 be amended to clarify.

e. Claim 15 is indefinite for the recitation "said reaction cell is filled at most half way with sample liquid" because it is unclear whether the recitation is a method step of "filling" or whether the recitation defines the contents of the reaction cell. It is suggested that the claim be amended to clarify.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Trulson et al (U.S. Patent No. 5,834,758, issued 10 November 1998).

Regarding Claim 8, Trulson et al disclose an array hybridization method comprising introducing a sample liquid into a reaction cell so that some of the interior volume is partially

Art Unit: 1634

occupied by sample liquid and partially occupied by gas (N₂ bubbles), centrifuging said sample liquid by rotating (i.e. circulate, Column 9, lines 37-40) said cell having a probe array so that centrifugal forces urge the sample liquid against the array and agitating said sample liquid in the reaction cell during centrifugation so that said sample liquid moves relative to the array (Column 9, line 27-50 and Column 14, lines 12-42).

8. Claim 8 is rejected under 35 U.S.C. 102(e) as being anticipated by Schembri et al (U.S. Patent No. 6,258,593, filed 30 June 1999).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claim 8, Schembri et al disclose an array hybridization method comprising introducing a sample liquid into a reaction cell so that some of the interior volume is partially occupied by sample liquid and partially occupied by gas (bubble), centrifuging (Column 11, lines 65-67 and Column 12, lines 25-30) said sample liquid by rotating said cell having a probe array so that centrifugal forces urge the sample liquid against the array and agitating (i.e. mixing e.g. nutating, Column 12, lines 1-2) said sample liquid in the reaction cell during centrifugation so that said sample liquid moves relative to the array (Column 11, line 53-Column 12, line 42).

9. Claims 8-13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al (U.S. Patent Application Publication No. 2002/0001803 A1, filed 20 July 1999).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claim 8, Smith et al disclose an array hybridization method comprising introducing a sample liquid into a reaction cell so that some of the interior volume is partially occupied by sample liquid and partially occupied by gas (i.e. the sample liquid within the cell incompletely fills the cell which would further be filled with air, ¶ 48 and Fig. 3) centrifuging said sample liquid by rotating said cell having a probe array so that centrifugal forces urge the sample liquid against the array and agitating said sample liquid in the reaction cell during centrifugation so that said sample liquid moves relative to the array (¶ 50-52 and Claims 1-5).

Regarding Claim 9, Smith et al disclose the method wherein the agitation involves rotating the sample cell about an axis that is more orthogonal to than along said centrifugal force i.e. not perpendicular (Claim 5).

Regarding Claim 10, Smith et al disclose the method wherein said agitating involves periodically changing the direction of rotation about the agitation axis (¶ 50, lines 16-22).

Regarding Claim 11, Smith et al disclose the method wherein the said centrifugation involves rotating said cell at a centrifuge rate greater than agitation rate (¶ 50).

Regarding Claim 12, Smith et al disclose the method wherein the agitation involves rotating said sample cell about an axis ("x") that extends parallel to the axis of centrifugal force (28) (Fig. 3 and ¶ 50).

Art Unit: 1634

Regarding Claim 13, Smith et al disclose the method wherein the array extends more orthogonal to centrifugal than along it so that the centrifugal forces use the sample liquid against the array (§ 50, lines 22-28 and Fig. 3).

Regarding Claim 15, Smith et al disclose the method wherein the reaction cell is filled at most half way with the sample liquid (Fig. 3).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trulson et al (U.S. Patent No. 5,834,758, issued 10 November 1998) in view of Holmes (U.S. Patent No. 5,527,681, issued 18 June 1996).

Regarding Claim 8, Trulson et al teach an array hybridization method comprising introducing a sample liquid into a reaction cell so that some of the interior volume is partially occupied by sample liquid and partially occupied by gas (N₂ bubbles), centrifuging said sample liquid by rotating (i.e. circulate, Column 9, lines 37-40) said cell having a probe array so that centrifugal forces urge the sample liquid against the array and agitating said sample liquid in the reaction cell during centrifugation so that said sample liquid moves relative to the array (Column 9, line 27-50 and Column 14, lines 12-42). Additionally, Holmes teaches a method comprising introducing a liquid sample into a reaction cell and a centrifuging by rotating said

Art Unit: 1634

reaction cell wherein said centrifuge substantially reduces the amount of reagents needed (Column 10, lines 14-23). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the centrifugation of Holmes et al to the method of Trulson et al to thereby reduce the amount of reagents needed as taught by Holmes (Column 10, lines 14-23) because the skilled practitioner in the art would have been motivated to reduce the amount of costly hybridization reagents to thereby maximize experimental results at minimal cost.

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trulson et al (U.S. Patent No. 5,834,758, issued 10 November 1998) in view of Holmes (U.S. Patent No. 5,527,681, issued 18 June 1996) as applied to Claim 8 above and further in view of Combs (U.S. Patent No. 4,812,294, issued 14 March 1989).

Regarding Claim 9, Trulson et al teaches the method wherein the sample fluid is agitated and circulated (Column 9, lines 37-40) but they do not teach an axis of centrifugation is more orthogonal to than along said centrifugal force. Combs teaches a similar method utilizing a reaction cell, a centrifuge and an agitator wherein said agitator rotates said reaction cell about an axis more orthogonal to than along said centrifugal force wherein said orthogonal axis allows fluid to flow as desired even under conditions of gravity (Abstract, lines 3-10). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify rotational axis of the agitator of Trulson et al with the more orthogonal axis as taught by Combs for the expected benefit of allowing the sample liquid to flow across the reaction cell under conditions of gravity as taught by Combs (Abstract).

13. Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trulson et al (U.S. Patent No. 5,834,758, issued 10 November 1998) in view of Holmes (U.S. Patent No. 5,527,681, issued 18 June 1996) and Combs (U.S. Patent No. 4,812,294, issued 14 March 1989) as applied to Claim 9 above and further in view of Klein (U.S. Patent No. 5,449,621, issued 12 September 1995).

Regarding Claim 10, Trulson et al teaches the method wherein the sample fluid is agitated and circulated to facilitate hybridization and shorten hybridization time (Column 9, lines 37-40) but they do not teach the agitator changes direction periodically. However, it was well known in the art at the time the claimed invention was made that agitators periodically change direction as taught by Klein who teaches that agitators change direction of rotation of a reaction cell relative to said rotor periodically so as to define an agitation cycle and improve mixing within the reaction cell (Column 5, lines 32-58). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the direction changing of Klein to the agitation of Trulson et al to thereby improve mixing within the reaction cell as taught by Klein (Column 5, lines 32-58) for the obvious benefits of maximizing interaction (mixing) of hybridization components and thereby optimizing hybridization results.

Regarding Claim 11, Klein teaches the apparatus wherein said rotor has a rotation rate greater than said agitation cycle rate (Column 5, lines 38-44).

Regarding Claims 12 and 13, Trulson et al is silent regarding agitation axis. However, Combs teaches the similar method wherein said agitation means rotates said reaction cell about an axis that extends more parallel than orthogonal to said centrifuge axis (Column 13, lines 30-35 and Fig. 11). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made apply the agitation axis of Combs to the method of

Art Unit: 1634

Trulson for the expected benefit of providing the desired fluid flow based on the processing cycle as taught by Combs (Column 13, lines 12-15).

Regarding Claim 14, Trulson et al teach the method further comprising removing sample liquid from the reaction cell wherein removing the liquid involves rotating (agitating) to for fluid away from the array (Column 14, lines 12-60).

Regarding Claim 15, Trulson et al teach the method wherein the reaction cell is filled at most half way with sample liquid i.e. N₂ is injected into the reaction cell until the amount of fluid in the container nears empty (Column 14, lines 34-42). At this point during the reaction, the reaction cell is filled at most half way with the sample liquid as claimed.

Double Patenting

14. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

15. Claims 8-15 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 8-15 of copending Application No. 09/971,867. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 8-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 09/729,169. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods comprising the steps of introducing a liquid into a reaction cell, centrifuging the sample by rotating the cell and agitating (mixing) the sample. The sets of claims differ only in the arrangement of limitations. For example, instant Claim 1 is drawn to an array hybridization method while Claim 1 of the '169 application is drawn to a method for contacting components and dependent Claim 12 limits the method to hybridization. As such, both sets of claims are drawn to similar methods which are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claim 8 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 51 of copending Application No.

Art Unit: 1634

09/900,294. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn to methods of hybridization comprising the steps of introducing a liquid into a reaction cell and maintaining conditions within the reaction cell to obtain hybridization. The sets of claims differ only in that the instant claim recites the hybridization condition (i.e. centrifuging the sample by rotating the cell and agitating the sample) while the '294 application relies on the disclosure to define identical conditions (i.e. centrifuging the sample by rotating the cell and agitating the sample, ¶ 82-84). As such, both claims are drawn to similar methods which are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Application/Control Number: 10/010,020

Page 13

Art Unit: 1634

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
May 28, 2003